2163. SHRI MANOJ BHATTACHARYA:—Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether quality or standard of drugs are being compromised due to the wide practice of third party manufacturing or manufacturing under loan licence system by many reputed companies;

(b) if so, whether Government envisage any measures to curb this; and

(c) if so, the measures being contemplated?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C.P. THAKUR): (a) As per the feed back available from State Licensing Authorities of Maharashtra, Orissa, Kerala, Goa, Karnataka, Delhi, Rajasthan, Chandigarh UT, Lakshadweep, Sikkim, no such incidence has come to their notice where quality or standards of drugs are being compromised due to third party manufacturing or manufacturing under loan licence system by reputed companies.

(b) and (c) The Drugs Controller General of India has asked all Pharmaceuticals, Industry Associations to convey any specific information about alleged spawning of fake drug trade due to misuse of loan license activity. All State Drugs Control Authorities have also been directed to convey specific information about such linkage, if any, observed by them in their State.

Departure from process patent regime

2164. SHRI MANOJ BHATTACHARYA : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :

(a) whether a departure from the process patent regime in respect of the manufacturing and availability of the essential drugs will adversely affect the prices of drug formulations; and

(b) if so, the concrete measures Government are contemplating to avert such serious problem?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C. P. THAKUR): (a) and (b) While the actual impact of change from the process patent regime for pharmaceuticals to a product patent regime cannot be gauged as there are no product patents at present for pharmaceutical products, it is generally felt that

change to a product patent regime may result in increase or prices of patented drugs which may be used for treating life threatening diseases.

The Joint Select Committee of Parliament is presently examining the Patents (Second) Amendment Bill, 1999 in consultation with various Departments in the Government and also non-governmental agencies in order to determine how the maximum possible safeguards can be built into the Patents Act in order to ensure that the prices of essential drugs are not adversely affected by an amendment of the Patents Act to bring in line with the TRIPS.

Flourishing spurious drugs trade

2165. SHRI KRISHNA KUMAR BIRLA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether due to lack in coordination between Government and State Governments the trade of spurious drugs is flourishing in the country;

(b) if so, whether the spurious drugs manufactured in a particular State is sold in other States resulting in confusion for the authorities to take any action;

(c) if so, whether Government propose to prepare any concrete action plan to check sale or manufacture of spurious drugs throughout the country; and

(d) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C. P. THAKUR): (a) and (b) Manufacture and sale of spurious medicines is a clandestine activity indulged in by some unscrupulous and anti-social persons.

Under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, a drug manufactured in one state by licensed firms can be sold or distributed in other States.

Government has been advising to State Governments from time to time to gear up their enforcement machinery to detect and unearth spurious/fake drugs moving in the inter-state commerce as well as speedy analysis of samples of drugs by their testing laboratories and to coordinate activities with other States.

(c) and (d) The Drugs Controller General (India) has advised the State Drugs Controllers to take the following measures for curbing the incidence of spurious drugs :